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(54) **COMPOSITIONS FOR REDUCING ENVIRONMENTAL SENSITIVITY AND REGULATING IMMUNE FUNCTION**

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See application file for complete search history.

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(57) **ABSTRACT**

The present invention is directed to compositions for improving immune function and sensitivities to the natural and man-made environment that include ingredients from natural sources. It is further directed to methods of administering the compositions and kits containing the compositions. In a composition aspect, the composition is for regulating immune function and non-immune related sensitivities. It consists essentially of: 2 weight percent to 95 weight percent Psoralea; 2 weight percent to 95 weight percent Scutellaria; and 2 weight percent to 95 weight percent Xanthium. The Scutellaria portion may be replaced by Gardenia (in equal measure), or by a mixture of Scutellaria and Gardenia.

4 Claims, No Drawings

COMPOSITIONS FOR REDUCING ENVIRONMENTAL SENSITIVITY AND REGULATING IMMUNE FUNCTION

CONTINUITY AND CLAIM OF PRIORITY

This is an original U.S. patent application.

FIELD

The present invention is directed to compositions for regulating the body's reaction to elements and conditions of the environment that may trigger immune and/or non-immune mediated reactions or sensitivities. Methods of administering the compositions and kits containing the compositions are also described. Embodiments are specifically directed to compositions that include ingredients from natural sources.

BACKGROUND

An eleven-ingredient immune-support formula was developed. The formula was shown to aid in the reduction of symptoms related to exposure to allergens and other elements of the environment that trigger immune and non-immune related symptoms affecting body systems from respiratory, digestive, as well as the dermis and epidermis. The ingredients of the formula are as follows: Psoralea fruit; Skullcap root; Xanthium fruit; Chrysanthemum flower; Gardenia fruit; Betelnut husk; Schisandra berry; Bupleurum root; Jujube seed; Plantain seed; and, Schizonepeta aerial parts.

Investigations and experience with the eleven-ingredient formula showed no primary ingredient in the formula or any one particularly responsible for many of the observed benefits. All ingredients were thought to play a supporting role in the composition.

While the prior-art formulation affords desirable outcomes with respect to environmental sensitivities and/or reactions, it is rather large in volume and relatively expensive to make. Furthermore, in view of the large number of ingredients, it was found to be difficult to hit consistency and standardized functionality (biologic activity) targets. An improved formulation that is more compact (less voluminous) and less expensive to make, but nevertheless offers similar beneficial effects against environmental sensitivities ranging from foods to pollen, dust, temperatures, air pollution, and other environmental irritants, may be of significant value in this field.

SUMMARY

The present invention is directed to compositions for improving immune and non-immune mediated environmental sensitivities that include ingredients from natural sources. It is further directed to methods of administering the compositions and kits containing the compositions.

The inventive compositions for regulating immune and non-immune related environmental sensitivities consist essentially of: 2 weight percent to 95 weight percent Psoralea; 2 weight percent to 95 weight percent Xanthium; and 2 weight percent to 95 weight percent of a third ingredient, which may be Gardenia, Scutellaria, or a mixture of these two ingredients (the mixture present at about 2 weight percent to 95 weight percent).

Formulations for packaging/delivering the inventive compositions for treating environmental sensitivities are also described and claimed. All of the delivery formulations include an effective dose the inventive composition, with non-active ingredients to permit the composition to be manufactured and provided in various convenient forms.

Embodiments of the inventive composition may be supplied as a kit, comprising either subsets of the active ingredients or the pre-mixed active ingredients, plus a set of instructions for compounding (if necessary), applying, evaluating and adjusting the dosage of the composition.

DETAILED DESCRIPTION

The present invention is directed to compositions for improving immune function and non-immune related environmental sensitivities that include ingredients from natural sources. It is further directed to methods of administering the compositions and kits containing the compositions.

Compositions

The compositions of the present invention include Psoralea, Scutellaria (and/or Gardenia, as discussed below) and Xanthium as active ingredients in various ratios. Typically, the composition comprises 2-95 wt. %), Scutellaria (2-95 wt. %), and Xanthium (2-95 wt. %) as active ingredients. Non-limiting examples of acceptable ratios of active ingredients present in effective compositions according to an embodiment are provided below:

Psoralea (% by weight)	*Scutellaria* (% by weight)	*Xanthium* (% by weight)
95 wt.	2 wt. %	3 wt.
95 wt.	3 wt. %	2 wt.
90 wt.	5 wt. %	5 wt.
85 wt.	5 wt. %	10 wt.
85 wt.	10 wt. %	5 wt.
80 wt.	10 wt. %	10 wt.
75 wt.	10 wt. %	15 wt.
75 wt.	15 wt. %	10 wt.
70 wt.	20 wt. %	10 wt.
70 wt.	15 wt. %	15 wt.
70 wt.	10 wt. %	20 wt.
65 wt.	25 wt. %	10 wt.
65 wt.	20 wt. %	15 wt.
65 wt.	15 wt. %	20 wt.
65 wt.	10 wt. %	25 wt.
60 wt.	30 wt. %	10 wt.
60 wt.	25 wt. %	15 wt.
60 wt.	20 wt. %	20 wt.
60 wt.	15 wt. %	25 wt.
60 wt.	10 wt. %	30 wt.
55 wt.	35 wt. %	10 wt.
55 wt.	30 wt. %	15 wt.
55 wt.	25 wt. %	20 wt.
55 wt.	20 wt. %	25 wt.
55 wt.	15 wt. %	30 wt.
55 wt.	10 wt. %	35 wt.
50 wt.	40 wt. %	10 wt.
50 wt.	35 wt. %	15 wt.
50 wt.	30 wt. %	20 wt.
50 wt.	25 wt. %	25 wt.
50 wt.	20 wt. %	30 wt.
50 wt.	15 wt. %	35 wt.
50 wt.	10 wt. %	40 wt.
45 wt.	45 wt. %	10 wt.
45 wt.	40 wt. %	15 wt.
45 wt.	35 wt. %	20 wt.
45 wt.	30 wt. %	25 wt.
45 wt.	25 wt. %	30 wt.
45 wt.	20 wt. %	35 wt.
45 wt.	15 wt. %	40 wt.
45 wt.	10 wt. %	45 wt.
40 wt.	50 wt. %	10 wt.
40 wt.	45 wt. %	15 wt.
40 wt.	40 wt. %	20 wt.
40 wt.	35 wt. %	25 wt.
40 wt.	30 wt. %	30 wt.
40 wt.	25 wt. %	35 wt.

-continued

Psoralea (% by weight)	*Scutellaria* (% by weight)	*Xanthium* (% by weight)
40 wt.	20 wt. %	40 wt.
40 wt.	15 wt. %	45 wt.
40 wt.	10 wt. %	50 wt.
35 wt.	55 wt. %	10 wt.
35 wt.	50 wt. %	15 wt.
35 wt.	45 wt. %	20 wt.
35 wt.	40 wt. %	25 wt.
35 wt.	35 wt. %	30 wt.
35 wt.	30 wt. %	35 wt.
35 wt.	25 wt. %	40 wt.
35 wt.	20 wt. %	45 wt.
35 wt.	15 wt. %	50 wt.
35 wt.	10 wt. %	55 wt.
30 wt.	60 wt. %	10 wt.
30 wt.	55 wt. %	15 wt.
30 wt.	50 wt. %	20 wt.
30 wt.	45 wt. %	25 wt.
30 wt.	40 wt. %	30 wt.
30 wt.	35 wt. %	35 wt.
30 wt.	30 wt. %	40 wt.
30 wt.	25 wt. %	45 wt.
30 wt.	20 wt. %	50 wt.
30 wt.	15 wt. %	55 wt.
30 wt.	10 wt. %	60 wt.
25 wt.	65 wt. %	10 wt.
25 wt.	60 wt. %	15 wt.
25 wt.	55 wt. %	20 wt.
25 wt.	50 wt. %	25 wt.
25 wt.	45 wt. %	30 wt.
25 wt.	40 wt. %	35 wt.
25 wt.	35 wt. %	40 wt.
25 wt.	30 wt. %	45 wt.
25 wt.	25 wt. %	50 wt.
25 wt.	20 wt. %	55 wt.
25 wt.	15 wt. %	60 wt.
25 wt.	10 wt. %	65 wt.
20 wt.	70 wt. %	10 wt.
20 wt.	65 wt. %	15 wt.
20 wt.	60 wt. %	20 wt.
20 wt.	55 wt. %	25 wt.
20 wt.	50 wt. %	30 wt.
20 wt.	45 wt. %	35 wt.
20 wt.	40 wt. %	40 wt.
20 wt.	35 wt. %	45 wt.
20 wt.	30 wt. %	50 wt.
20 wt.	25 wt. %	55 wt.
20 wt.	20 wt. %	60 wt.
20 wt.	15 wt. %	65 wt.
20 wt.	10 wt. %	70 wt.
15 wt.	75 wt. %	10 wt.
15 wt.	70 wt. %	15 wt.
15 wt.	65 wt. %	20 wt.
15 wt.	60 wt. %	25 wt.
15 wt.	55 wt. %	30 wt.
15 wt.	50 wt. %	35 wt.
15 wt.	45 wt. %	40 wt.
15 wt.	40 wt. %	45 wt.
15 wt.	35 wt. %	50 wt.
15 wt.	30 wt. %	55 wt.
15 wt.	25 wt. %	60 wt.
15 wt.	20 wt. %	65 wt.
15 wt.	15 wt. %	70 wt.
15 wt.	10 wt. %	75 wt.
2 wt.	95 wt. %	3 wt.
3 wt.	95 wt. %	2 wt.
5 wt.	90 wt. %	5 wt.
5 wt.	85 wt. %	10 wt.
10 wt.	85 wt. %	5 wt.
10 wt.	80 wt. %	10 wt.
10 wt.	75 wt. %	15 wt.
10 wt.	70 wt. %	20 wt.
10 wt.	65 wt. %	25 wt.
10 wt.	60 wt. %	30 wt.
10 wt.	55 wt. %	35 wt.
10 wt.	50 wt. %	40 wt.
10 wt.	45 wt. %	45 wt.

-continued

Psoralea (% by weight)	*Scutellaria* (% by weight)	*Xanthium* (% by weight)
10 wt.	40 wt. %	50 wt.
10 wt.	35 wt. %	55 wt.
10 wt.	30 wt. %	60 wt.
10 wt.	25 wt. %	65 wt.
10 wt.	20 wt. %	70 wt.
10 wt.	15 wt. %	75 wt.
10 wt.	10 wt. %	80 wt. %
10 wt.	5 wt. %	85 wt.
5 wt.	10 wt. %	85 wt.
5 wt.	5 wt. %	90 wt.
3 wt.	2 wt. %	95 wt.
2 wt.	3 wt. %	95 wt. %

The "Scutellaria" fraction in the composition tables may be satisfied, at least in part, by either Scutellaria or Gardenia or a mixture of Scutellaria and Gardenia. Either ingredient or a mixture of the two ingredients may be substituted for Scutellaria alone.

Compositions of the present invention may take different forms for delivery (i.e., ingestion), depending on the exact formulation employed. Nonlimiting examples include:

- Capsules with the addition of flour, starch, modified starch, maltodextrin, cellulose, modified cellulose, protein hydrolysate, rice powder, whey powder, calcium phosphate, calcium carbonate, lactose, saccharides, sorbitol, mannitol, xylitol, stearic acid, stearate, silica, silicate, polyethylene glycol, flavors, and/or colors, among others.
- Tablets with the addition of starch, modified starch, maltodextrin, cellulose, methylcellulose, ethylcellulose, hydroxypropylmethylcellulose, modified cellulose, protein hydrolysate, rice powder, whey powder, calcium phosphate, calcium carbonate, lactose, sweeteners (e.g. sucrose, fructose, glucose, corn syrup, saccharides, saccharine, sucralose, aspartame, etc.), sorbitol, mannitol, xylitol, (gum tragacanth, gum arabic, agar, guar gum, locust bean gum, karaya gum, xanthan gum, etc.) zein, saccharides, stearic acid, stearate, silica, silicate, polyethylene glycol, pharmaceutical glaze, wax, flavors, and/or colors, among others.
- Powdered drink mix with the addition of starch, modified starch, maltodextrin, cellulose, modified cellulose, protein hydrolysate, whey powder, calcium phosphate, calcium carbonate, lactose, sorbitol, mannitol, xylitol, sweeteners (e.g. sucrose, fructose, glucose, corn syrup, saccharides, saccharine, sucralose, aspartame, etc.), stearic acid, stearate, silica, silicate, flavors, and/or colors, among others.
- Ready-to-drink beverages with the addition of starch, modified starch, maltodextrin, cellulose, modified cellulose, protein hydrolysate, whey powder, calcium phosphate, calcium carbonate, lecithin, sweeteners (e.g. sucrose, fructose, glucose, corn syrup, saccharides, saccharine, sucralose, aspartame, etc.), sorbitol, mannitol, xylitol, silica, silicate, solvents (e.g. water, ethanol, polyethylene glycol, propylene glycol, glycerin), acidifiers (e.g. citric acid, acetic acid, malic acid, tartaric acid), citrate, preservatives (e.g. benzoic acid, benzoate, sorbic acid, sorbate, polysorbate, propionic acid, propionate, nisin), caffeine, flavors, and/or colors, among others.
- Semisolids such as Gu™ with the addition of starch, modified starch, maltodextrin, cellulose, modified cellulose, protein hydrolysate, whey powder, calcium phosphate,

calcium carbonate, lecithin, oil, partially hydrogenated oil, fat, milk, milk solids, mono- or diglycerides, polysorbates, sorbitan monostearate, (gum tragacanth, gum arabic, agar, guar gum, locust bean gum, karaya gum, xanthan gum, etc.), sweeteners (e.g. sucrose, fructose, glucose, corn syrup, saccharides, saccharine, sucralose, aspartame, etc.), sorbitol, mannitol, xylitol, silica, silicate, solvents (e.g. water, ethanol, polyethylene glycol, propylene glycol, glycerin), acidifiers (e.g. citric acid, acetic acid, malic acid, tartaric acid), citrate, preservatives (e.g. benzoic acid, benzoate, sorbic acid, sorbate, polysorbate, propionic acid, propionate, nisin, parabens), flavors, and/or colors, among others.

Softgel capsules with the addition of lecithin, oil, wax, glycerine, gelatin, propylene glycol, polyethylene glycol, and/or colors, among others.

Food or supplement bars with the addition of flour, starch, modified starch, maltodextrin, cellulose, methylcellulose, ethylcellulose, hydroxypropylmethylcellulose, modified cellulose, protein hydrolysate, whey powder, calcium phosphate, calcium carbonate, lecithin, mono- or diglycerides, polysorbates, sorbitan monostearate, binders (gum tragacanth, gum arabic, agar, guar gum, locust bean gum, karaya gum, xanthan gum, etc.), sweeteners (e.g. sucrose, fructose, glucose, corn syrup, saccharides, saccharine, sucralose, aspartame, etc.), sorbitol, mannitol, xylitol, silica, silicate, solvents (e.g. water, ethanol, polyethylene glycol, propylene glycol, glycerin), acidifiers (e.g. citric acid, acetic acid, malic acid, tartaric acid), citrate, preservatives (e.g. benzoic acid, benzoate, sorbic acid, sorbate, polysorbate, propionic acid, propionate, nisin, BHA, BHT, EDTA, TBHQ, etc.), flavors, and/or colors, among others.

In the foregoing sample delivery forms, the active ingredients are mixed with and/or contained by ingredients or materials having no significant active properties relative to the purposes of the inventive composition. The active ingredients are measured by weight percentages relative to the total weight of active ingredients, not the total weight of active plus inactive ingredients.

Indications

Compositions of the present invention are taken by individuals experiencing a wide range of symptoms (and may be taken prophylactically as well). Characteristics of such individuals include:

a. People who are experiencing one or more symptoms of an impending or fully established allergic or non-allergic sensitivity, including structural or functional disorders such as respiratory congestion, especially nasal congestion and/or excess nasal discharge, sneezing, itchiness, scratchy throat, excessive ocular discharge, stiff neck, skin irritations, diminished breathing capacity, or post-meal digestive discomfort.

b. People who wish to take preventative measures to reduce the likelihood of experiencing environmental sensitivity reactions.

c. People who have depressed their immune system or general health status through exposure to cold weather, heightened physical exertion or other physical stresses such as physical work or exercise, sleeplessness or irregular sleep habits, emotional stress, prolonged illness, or immune function and general health degradation that naturally occurs as part of the aging process.

d. People who want to strengthen their immune and other body systems against exposure to cold weather, environmental irritants, heightened physical exertion or other physical stresses such as physical work or exercise, sleeplessness or irregular sleep habits, emotional stress, prolonged illness, or immune function and general health degradation that naturally occurs as part of the aging process. People who want to support their body's ability to healthfully adapt to an environment or improve the resilience of their health to new, changing or challenging circumstances physically, emotionally, mentally.

Typical individual consumption of the inventive composition ranges from about 450 mg to about 1800 mg of an embodiment (i.e., 450-1800 mg of active ingredients) once to three times per day, depending on the status of immune function, general health, and other factors such as exposure or activity levels.

Compositions of the present invention provide one with general well-being and improved responses to environmental irritants and dietary sensitivities. The expected benefits for a majority of those who are experiencing the symptoms of environmental sensitivities are the reduction or cessation of one or more of the symptoms. Some may experience a reversal or cessation of all symptoms within 10 to 60 minutes.

Kits

The various delivery systems for compositions of the present invention can be packaged in a number of ways as appropriate, including but not limited to:

Bottle with label and/or insert having instructions

Foil laminate pouch with instructions

Wrapper with instructions

Carton or box with instructions and/or label with instructions and/or insert with instructions

Sample Instructions

For prevention, Adults take 450 mg-900 mg of the formulation once a clay, 4 to 5 clays per week. At the first indication of the symptoms of environmental sensitivity, Adults take 900 to 1800 mg of the blend every 2 to 8 hours as needed until symptoms are significantly reduced. If you are taking a prescription medication or are pregnant or lactating, consult with your doctor before taking the formulation.

EXPERIMENTAL RESULTS

Example 1

Numerous subjects tested using the BioRim™ medium throughput method in a clinical setting over a period of years with PSX (i.e., the Psoralea, Scutellaria and Xanthium composition of an embodiment) or PGX (Psoralea, Gardenia and Xanthium of another embodiment) showed marked improvement in immune and non-immune related response to symptoms of environmental sensitivity within 10 to 60 minutes. The same subjects were tested using control, placebo and the individual ingredients of PSX/PGX. The ingredients individually had little to no effect in relieving or protecting the subjects' biological systems against environmental sensitivities. The PSX and PGX formulations of the three combined ingredients showed a significant improvement in both immune and non-immune related response in all subjects.

The applications of the present invention have been described largely by reference to specific formulations of the three active ingredients (where one of the three may be chosen from between two alternatives, or as a mixture of the two alternative ingredients). However, those of skill in the art will recognize that the active ingredients of an embodiment may be combined with other ingredients having different purposes or active mechanisms to produce a composition that provides

multiple therapeutic benefits. Such compositions are understood to be captured according to the following claims.

We claim:

1. A medicinal composition, consisting of:

Psoralea, Scutellaria and Xanthium as PSX active ingredients, wherein

the Psoralea is present at between 2% and 95% by weight of a total weight of PSX active ingredients,

the Xanthium is present at between 2% and 95% by weight of the total weight of PSX active ingredients, and

the Scutellaria is present at between 2% and 95% by weight of the total weight of PSX active ingredients,

in the form of a capsule.

2. A medicinal composition consisting of:

Psoralea as a first active ingredient, said first active ingredient present at between 2% and 95% by weight of a total weight of active ingredients;

Xanthium as a second active ingredient, said second active ingredient present at between 2% and 95% by weight of the total weight of active ingredients; and

a third active ingredient selected from the group consisting of Scutellaria, Gardenia and a mixture thereof, said third active ingredient present at between 2% and 95% of the total weight of active ingredients, in the form of a tablet.

3. The medicinal composition of claim **2** wherein the third active ingredient is exclusively Scutelleria.

4. The medicinal composition of claim **2**, packaged into a kit containing:

the three active ingredients in either a bottle or a foil laminate pouch; and

an instruction sheet providing dosing parameters.

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